



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,010	10/19/2001	Takehito Ito	0020-4914P-SP	7105
2292	7590	04/18/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			GLASS, RUSSELL S	
			ART UNIT	PAPER NUMBER

3626

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,010

Applicant(s)

ITO ET AL.

Examiner

Russell S. Glass

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 5, 8, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 11 recite the newly added limitation "if no necessity of emergency treatment is recognized". These claims recite a conditional limitation. There is no requirement within claims 8 and 11 that the limitation must occur. It is unclear to the examiner what happens if necessity of emergency treatment is recognized. Applicant is requested to clarify what happens in this scenario within these claims.

Claim 5 recites the newly added limitation "if the user terminal determines that the biological information is defective". These claims recite a conditional limitation. There is no requirement within claim 5 that the limitation must occur. It is unclear to the examiner what happens if necessity of emergency treatment is recognized. Applicant is requested to clarify what happens in this scenario within these claims.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackson, (U.S. Pub. 2004/0078220).

1. As per claim 1, Jackson discloses a medical diagnosis system comprising:

at least one user terminal, operated by a user (Jackson, Figs. 2, 3a, 3b, 7; ¶ 60-62) (disclosing medical devices that constitute the detecting and monitoring units of the user terminal being applied by the patient);

center equipment located in a medical center for receiving and processing the medical information sent by the user from said user terminal, (Jackson, Fig. 7; ¶ 40, 92) (disclosing a central server that can be located anywhere within the network, including a medical center); and

at least one physician terminal for communicating with said center equipment to exchange the medical information, (Jackson, Fig. 7; ¶ 40, 92, 100) (disclosing a physician terminal in the form of a hand-held computer for network communication);

said user terminal including:

a detecting biological unit for detecting biological information of a user in the form of electric signals, (Jackson, Figs. 2, 3a, 3b, 7; ¶ 60-62) (disclosing medical devices that constitute the detecting and monitoring units of the user terminal being applied by the patient),

a monitoring unit for monitoring circumstances of detection, (Jackson, Figs. 2, 3a, 3b, 7; ¶ 60-62) (disclosing medical devices that

constitute the detecting and monitoring units of the user terminal being applied by the patient),

a user terminal communication unit for sending the user's medical information including the detected biological information to said center equipment, and for receiving the medical information from the center equipment, (Jackson, Figs. 2, 3a, 3b, 7; ¶¶ 60-62) (disclosing medical devices that interface with a central network for the purpose of treatment and diagnosis using analog and digital signals);

said center equipment including:

a first data storage unit for storing medical treatment information about a plurality of users and information about a plurality of physicians, (Jackson, Fig. 7, ¶¶ 64-67) (disclosing storage of an electronic medical record),

a medical center communications unit for receiving said user's medical information sent from said user terminal equipment, (Jackson, ¶¶ 70-72),

a data-analyzing unit for analyzing said user's medical information received by said center communications unit and producing an analyzed result, (Jackson, ¶¶ 70-77) (performing diagnosis and treatment based on medical information received is considered to be an analyzed result),

a control unit for producing a diagnostic result corresponding to the

analyzed result of said user's medical information, (Jackson, ¶ 70-77)
(performing diagnosis and treatment based on medical information received is
considered to be an analyzed result),

a second data storage-means unit for storing doctor's questions
selectable according to the analyzed result, (Jackson, ¶ 70-77) (prompting
for feed back is equivalent to questioning since it performs an identical
function in substantially the same way and produces substantially the
same results),

a data extracting unit for reading selected ones of the doctor's
questions from said second data storage unit, and for selecting at least
one physician among said plurality of physicians stored in said first data
storage unit, (Jackson, Figs. 3A, 3B ¶ 18, 19, 23, 30, 55-59, 70-81)
(disclosing using patient responses to questions to determine whether a
physician is required and selecting a physician),

the medical center communications unit for communicating with
said user terminal and/or said physician terminal to send said medical
information including said diagnostic result and said selected ones of the
doctor's questions, to receive answers from said user terminal to said
selected ones of the doctor's questions, and to send an advice to the user
to have a close examination along with a message of introduction of a
suitable physician when the diagnostic result indicates a non-emergency
abnormality condition, (Jackson, Figs. 3A, 3B; ¶ 18, 19, 23, 30, 55-59, 70-

81) (disclosing using patient responses to questions to determine whether a physician is required, selecting a physician, performing treatment, and providing prescriptions);

said physician terminal including:

a physician communication unit for receiving said user's medical information sent from said center equipment, and also for sending said user's medical information of the physician side to said center equipment, (Jackson, Fig. 7; ¶ 40, 92, 100) (disclosing a communication unit in the form of a hand-held computer for performing network functions, including sending and receiving).

Furthermore, Claim 1 is replete with limitations that merely constitute the intended use of the system hardware. For example, claim 1 contains the limitation "a user terminal unit for sending the user's medical information". Any disclosure of a user terminal communication unit is capable of performing the limitations disclosed by the claim. Therefore, the intended use of the system has not been considered because it fails to further limit the system claim, (see MPEP 2106). For examination purposes only, citations have been provided that reference the claimed intended use of the claimed system.

2. As per claim 2, Jackson discloses a diagnostic processing method comprising the steps of:

analyzing medical information of a user sent from a user terminal, (Jackson, Figs. 3A, 3B; ¶ 18, 19, 23, 30, 55-59, 70-81) (disclosing using patient responses to questions to determine whether a physician is required, selecting a physician, performing diagnosis and treatment, and providing prescriptions);

carrying on diagnosis of the user who had been determined as being abnormal but requiring no emergency treatment, by use of a diagnostic result based on said biological information in combination with received answers to a doctor's questions selected based on an analyzed result, the received answers to the doctor's questions also being sent by the user from the user terminal, (Jackson, Figs. 3A, 3B; ¶ 18, 19, 23, 30, 55-59, 70-81) (disclosing using patient responses to questions to determine whether a physician is required, selecting a physician, performing diagnosis and treatment, and providing prescriptions); and

sending an advice to the user to have a close examination along with a message of introduction of a suitable physician, (Jackson, Figs. 3A, 3B; ¶ 18, 19, 23, 30, 55-59, 70-81) (disclosing using patient responses to questions to determine whether a physician is required, selecting a physician, performing diagnosis and treatment, and providing prescriptions).

3. As per claim 3, Jackson discloses a diagnostic processing method further comprising the steps of:

analyzing the user's medical information sent from the user terminal to determine the health condition of the user categorized into three cases, (a) not particular, (b)

Art Unit: 3626

abnormal but no need to emergency care, and (c) abnormal and need to emergency care, (Jackson, Figs. 3A, 3B; ¶¶ 18, 19, 23, 30, 55-59, 70-81);

sending a determined result to the user in case of the category (a), and sending the doctor's questions determined based on said analyzed results to the user to request answers to said doctor's questions in case of the category (b), and sending a request for medical treatment to a suitable physician selected based on said analyzed result in case of the category (c), (Jackson, Figs. 3A, 3B; ¶¶ 18, 19, 23, 30, 55-59, 70-81) (disclosing prompting the patient and /or medical device for more information and based on information provided, either providing information, asking for more information, and requesting medical treatment);

wherein, in case of the category (b), said method further including the steps of analyzing the received answers to said doctor's questions to determine a health condition of the user categorized into three cases, (a) not particular, (b) abnormal but no need for emergency care, and (c) abnormal and need for emergency care; and sending the determined result along with health advice to the user in case of the category (a), and sending a request for medical treatment to a suitable physician selected based on said determination in case of said category (c), (Jackson, Figs. 3A, 3B; ¶¶ 18, 19, 23, 30, 55-59, 70-81) (disclosing prompting the patient and /or medical device for more information and based on information provided, either providing information, asking for more information, and requesting medical treatment).

Furthermore, Claim 3 is replete with limitations that merely suggest or make optional use of the system hardware. For example, claim 1 contains the limitation

Art Unit: 3626

"wherein, in case of the category (b), said method further including the steps of analyzing the received answers to said doctor's questions to determine a health condition of the user categorized into three cases". Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation, (see MPEP 2106, 2111.04). For examination purposes only, citations have been provided that reference the claimed intended use of the claimed system.

4. As per claim 4, Jackson discloses a medical diagnosis system wherein the monitoring unit of the user terminal allows the user to observe the detected information, (Jackson, ¶ 60-62) (disclosing monitoring unit thermometer or sphygmomanometer that would allow the user to observe detected information).

Furthermore, Claim 4 is replete with limitations that merely suggest or make optional use of the system hardware. For example, claim 1 contains the limitation **"wherein** the monitoring unit of the user terminal allows the user to observe the detected information". Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation, (see MPEP 2106, 2111.04). For examination purposes only, citations have been provided that reference the claimed intended use of the claimed system.

Art Unit: 3626

5. As per claim 5, Jackson discloses a medical diagnosis system wherein if the user terminal determines that the biological information is defective, the user terminal gives a signal to the detecting biological unit to repeat the detection of the biological information until complete biological data are obtained, (Jackson, Figs. 3A b , 3B; ¶¶ 76, 77) (disclosing that if treatment, including the collection of biological information, is not complete, then the network, including the user terminal, will prompt the medical device to repeat the detection of the biological information until complete biological data are obtained, i.e. treatment completed).

Furthermore, Claim 5 is replete with limitations that merely suggest or make optional use of the system hardware. For example, claim 1 contains the limitation “**wherein** if the user terminal determines that the biological information is defective”. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation, (see MPEP 2106, 2111.04). For examination purposes only, citations have been provided that reference the claimed intended use of the claimed system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being anticipated by Jackson, (U.S. Pub. 2004/0078220) in view of Bayne, (U.S. Pub. 2005/0060198).

6. As per claim 6, Jackson fails to expressly disclose a medical diagnosis system, the user terminal further comprising an input/output unit constructed so that the user's medical information including the biological information can be written therein.

However, such a system is well-known in the art as disclosed by Bayne, (Bayne, ¶ 24-29, 40, 41) (disclosing a user terminal and a clinician device with a digitizing pen that would allow the user's medical information including the biological information to be written in).

It would be obvious to one of ordinary skill in the art to incorporate the digitizing pen from the clinician unit into the user terminal. The motivation would be to pre-equip the patient's home with equipment to allow physicians to make house calls without carrying burdensome equipment, (Bayne, ¶ 28).

7. As per claim 7, Jackson fails to expressly disclose a medical diagnosis system, the user terminal further comprising an input/output unit constructed so that the user is able to input written answers to the selected ones of the doctor's questions. However, such a system is well-known in the art as disclosed by Bayne, (Bayne, Fig. 4, 5; ¶ 24-29, 40, 41, 69-84) (disclosing inputting answers to the selected ones of the doctor's

Art Unit: 3626

questions, a user terminal and a clinician device with a digitizing pen that would allow the user's medical information including the answers to the selected ones of the doctor's questions to be written in).

It would be obvious to one of ordinary skill in the art to incorporate the digitizing pen from the clinician unit into the user terminal to allow the patient to write in answers to triage questions. The motivation would be to pre-equip the patient's home with equipment to allow physicians to make house calls without carrying burdensome equipment, (Bayne, ¶ 28).

8. As per claim 8, Jackson fails to expressly disclose a medical diagnosis system, wherein the center equipment is adapted to terminate a diagnostic process, if no necessity of emergency treatment is recognized, and the sending of the selected ones of the doctor's questions has been confirmed. However, such a system is well-known in the art as disclosed by Bayne, (Bayne, Abstract, Fig. 4, 5; ¶ 68-98) (disclosing the termination of diagnostic processing of triage questions if no emergency is found) (sending of the selected ones of the doctor's questions is confirmed by the request more information function that reiterates the triage protocol until a response is received).

Furthermore, the claim limitation "wherein the center equipment is adapted to terminate a diagnostic process" merely constitutes the intended use of the system hardware, and is only claimed in such terms as to suggest or makes optional the claimed limitation. In Bayne, the disclosed system is capable of terminating a diagnostic process and sending selected one's of the doctor's questions as disclosed by

Art Unit: 3626

the claim, (Bayne, Abstract, Fig. 4, 5; ¶ 68-98). Therefore, the intended use of the system has not been considered because it fails to further limit the system claim, (see MPEP 2106, 2111.04). For examination purposes only, citations have been provided that reference the claimed intended use of the claimed system.

9. As per claim 9, Jackson fails to expressly disclose a diagnostic processing method, further comprising the step of enabling the user to enter the user's medical information including the biological information in written form. However, such a system is well-known in the art as disclosed by Bayne, (Bayne, Fig. 4, 5; ¶ 24-29, 40, 41, 69-84) (disclosing inputting answers to the selected ones of the doctor's questions, a user terminal and a clinician device with a digitizing pen that would allow the user's medical information, including the biological information, to be written in).

It would be obvious to one of ordinary skill in the art to incorporate the digitizing pen from the clinician unit into the user terminal to allow the user to write in the user's medical information including the biological information. The motivation would be to pre-equip the patient's home with equipment to allow physicians to make house calls without carrying burdensome equipment, (Bayne, ¶ 28).

10. As per claim 10, Jackson fails to expressly disclose a diagnostic processing method, further comprising the step of enabling the user to enter answers to the selected ones of the doctor's questions in written form. However, such a system is well-

Art Unit: 3626

known in the art as disclosed by Bayne, (Bayne, Fig. 4, 5; ¶ 24-29, 40, 41, 69-84) (disclosing inputting answers to the selected ones of the doctor's questions, a user terminal and a clinician device with a digitizing pen that would allow the user's medical information including the answers to the selected ones of the doctor's questions to be written in).

It would be obvious to one of ordinary skill in the art to incorporate the digitizing pen from the clinician unit into the user terminal to allow the patient to write in answers to triage questions. The motivation would be to pre-equip the patient's home with equipment to allow physicians to make house calls without carrying burdensome equipment, (Bayne, ¶ 28).

11. As per claim 11, Jackson fails to expressly disclose a diagnostic processing method, further comprising the step of terminating the diagnostic processing if no necessity of emergency treatment is recognized and sending of the doctor's questions has been confirmed. However, such a system is well-known in the art as disclosed by Bayne, (Bayne, Abstract, Fig. 4, 5; ¶ 68-98) (disclosing the termination of diagnostic processing of triage questions if no emergency is found) (sending of the selected ones of the doctor's questions is confirmed by the request more information function that reiterates the triage protocol until a response is received).

Response to Arguments

Applicant's arguments filed January 9, 2006 have been fully considered but they are not persuasive for the reasons listed above in the rejection of amended claims 1-11, and those reasons further discussed below.

Applicant argues on page 12, 1st ¶, that "Jackson provides no hint of a data extracting unit for reading selected ones of the doctor's questions from said second data storage unit". However, Jackson clearly discloses a series of triage questions sent to the patient and an associated treatment tree wherein new questions are selected from storage on a database and presented to the patient. (Jackson, Fig. 7, ¶ 72-74). This system is considered to be equivalent to a data extracting unit since it performs an identical function in substantially the same way, i.e, asking treatment questions, and produces substantially the same results, i.e. a diagnosis.

Applicant further argues on page 12, ¶ 2 that "Jackson provides no hint of send an advice to the user to have a close examination along with a message of introduction of a suitable physician when the diagnostic result indicates a non-emergency abnormality condition". However, Jackson clearly discloses that if there is no emergency, the system will schedule an appointment with the patient's primary health provider or another provider selected from a backup list by the patient, (Jackson, ¶ 74). This is considered to be equivalent to send an advice to the user to have a close examination along with a message of introduction of a suitable physician since it performs an identical function in substantially the same way, i.e, asking treatment questions and recommending treatment, and produces substantially the same results, i.e. a non-emergency diagnosis and appointment for treatment by a suitable physician.

Furthermore, the claim limitations argued by applicant merely constitute the intended use of the data extracting unit and medical center communications unit. In Jackson, the disclosed system is capable of performing the functions as disclosed by the claim, (Jackson, Figs. 3A, 3B; ¶ 18, 19, 23, 30, 55-59, 70-81). Therefore, the intended use of the system has not been considered because it fails to further limit the system claim, (see MPEP 2106). For examination purposes only, citations have been provided that reference the claimed intended use of the claimed system, (see rejection of claim 1 and above).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure is as provided in the Tallman et al., Medical Network Management System and Process, (U.S. 5,471,382), issued on November 28, 1995; Iliff, Computerized Medical Advice System and Method Including Meta Function, (U.S. 5,711,297), issued on January 27, 1998; Kieval et al., Implantable Medical Device for Tracking Patient Cardiac Status, (U.S. 6,190,324), issued February 20, 2001; Iliff, Computerized Medical Diagnostic and Treatment Advice System Including Network Access, (Pub. No.: 2001/0029322), published on October 11, 2001; Victor, Method for Delivering Healthcare Services, (Pub. No.: 2002/0042724), published on April 11, 2002; Glodenberg, Virtual Doctor Interactive Cybernet System, (Pub. No.: 2002/006582), published on May 30, 2002; Riff et al., Medical Device Systems Implemented Network Scheme For Remote Patient Management, (Pub. No.: 2002/0082480), published on June 27, 2002; Argenbright et al., Patient Diagnosis Using Triage Protocols That Have

Customized Messages at Exit Points, (Pub. No.: 2003/0208377) , published on November 6, 2003; Iliff, Authoring Language Translator, (U.S. 6,748,353), issued on June 8, 2004; Pestonik et al., Systems and Methods For Manipulating Medical Data Via a Decision Support System, (Pub. No.: 2004/0260666), published on December 23, 2004; Riff et al., Medical Device Systems Implemented Network Scheme for Remote Patient Management, (Pub. No.: 2005/0021370), published on January 27, 2005; Zayas, Jr., System and Method for Conducting a Physician-Patient Consultation, (U.S. 6,850,889), issued on February 1, 2005.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell S. Glass whose telephone number is 571-272-3132. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 3626

RSG
3/28/2006

756


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER